IBUGESIC PLUS Oral Suspension (Ibuprofen + Paracetamol)

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Blackbox Warning

Hepatotoxicity
Paracetamol has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of paracetamol (acetaminophen) at doses that exceed 4000 mg per day, and often involve more than one acetaminophen-containing product.

Cardiovascular Risk
NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Ibugesic Plus Suspension is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk
NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Qualitative And Quantitative Composition

Ibugesic Plus Suspension (Strawberry Flavour)
Each 5 ml contains:
Ibuprofen IP..............................100 mg
Paracetamol IP..........................162.5 mg
Flavoured Syrup base...............q.s.
Colour: Erythrosine

Ibugesic Plus Suspension (Orange Flavour)
Each 5 ml contains:
Ibuprofen IP..............................100 mg
Paracetamol IP..........................162.5 mg
Flavoured Syrup base...............q.s.
Colour: Sunset Yellow FCF

Dosage Form(S) And Strength (S)

Suspension for oral use 60ml and 100ml
Clinical Particulars

Therapeutic Indications

Ibugesic Plus is indicated in the treatment of minor aches and pains and for reduction of fever.

Posology & Method of Administration

<table>
<thead>
<tr>
<th>Age group</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants 3 - 6 months (weighing more than 5 kg) *</td>
<td>2 - 2.5ml dose may be taken 3 times daily</td>
</tr>
<tr>
<td>&gt;6 months - 12 months</td>
<td>2 - 2.5ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>1- 4 years</td>
<td>4 - 4.5ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>4 - 7 years</td>
<td>4 - 8ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>7 - 10 years</td>
<td>8 - 10ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>10 -12 years</td>
<td>8 - 15ml dose may be taken 3 to 4 times daily</td>
</tr>
</tbody>
</table>

*Infants under 3 months of age or weighing less than 5 kg should not take Ibuprofen due to lack of data on safety and efficacy.

or as directed by the physician.

Contraindication

This combination is contraindicated for use:
- In patients with known hypersensitivity reaction to paracetamol, ibuprofen, other NSAIDs or to any of the excipients of this product.
- In patients with active alcoholism as chronic excessive alcohol ingestion may predispose patients to hepatotoxicity (due to the paracetamol component).
- In patients who have experienced asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid or other NSAIDs.
- In patients with active or history of gastrointestinal bleeding or peptic ulceration.
- In patients with severe heart failure (NYHA Class IV), hepatic failure or renal failure.
- In patients with cerebrovascular or other active bleeding.
- In patients with blood-formation disturbances.
- During the last trimester of pregnancy.
- Significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).

This product should not be taken with other products containing paracetamol, ibuprofen, acetylsalicylic acid, salicylates or with any other anti-inflammatory medicines unless under a doctor’s instruction.

Special Warnings & Precaution for Use

Paracetamol
Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with (non-cirrhotic) alcoholic liver disease.

Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

Ibuprofen
The elderly has an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis. Renal impairment as renal function may further deteriorate. There is a risk of renal impairment in dehydrated children and adolescents. **Hepatic dysfunction** Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) – as these conditions may be exacerbated. The use of Ibugesic Plus Oral Suspension with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration. There is limited evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment. GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events. Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment. Caution should be advised in patients receiving concomitant medications which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or antiplatelet agents such as aspirin. When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Administration of NSAID'S such as Ibuprofen may cause dose dependent renal toxicity in patients with reduced renal blood flow or blood volume where renal prostaglandins support the maintenance of renal perfusion. Patients at risk of this reaction include those with impaired renal function, heart failure or liver dysfunction. This is of importance in hypertension and/or cardiac impairment as renal function may deteriorate and/or fluid retention occur. Caution is therefore required in the use of Ibuprofen in such patients. Ibuprofen should be used with caution in patients with bronchial asthma or allergic disease, since such patients may have NSAID – sensitive asthma which has been associated with severe bronchospasm. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. **Cardiovascular and Cerebrovascular Effects** Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patient with history of hypertension and/or heart failure as fluid retention; hypertension and oedema have been reported in association with NSAIDs therapy. Clinical studies suggest that use of Ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤1200 mg/day) is associated with an increased risk of arterial thrombotic events. Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen
after careful consideration and high doses (2400 mg/day) should be avoided. Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Severe skin reactions

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk for these reactions early during therapy: the onset of the reaction occurring in most cases within the first month of treatment. Acute generalized exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Ibuprofen 100mg/5ml Oral Suspension should be discontinued at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesion, or any other sign of hypersensitivity.

Exceptionally, varicella can be at the origin of serious cutaneous and soft tissues infectious complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of ibuprofen in case of varicella (chickenpox).

Drugs interactions

The following interactions of paracetamol with other medicines have been noted:

- Drugs which induce hepatic microsomal enzymes such as alcohol.
- Concomitant barbiturates and tricyclic antidepressants may increase the hepatotoxicity of Paracetamol particularly after overdose.
- Anti-convulsant or oral steroid contraceptives can reduce serum levels of Paracetamol by liver enzyme induction.
- The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.
- The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of Paracetamol with increased risk of bleeding; occasional doses have no significant effect.

The following interactions of ibuprofen with other medicines have been noted:

- Acetylsalicylic acid (Aspirin): Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects.
- Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use.
- Other NSAIDs including cyclooxygenase-2 selective inhibitors: avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects.
- Ticlopidine: NSAIDs should not be combined with ticlopidine due to a risk of an additive effect in the inhibition of the platelet function.
- Methotrexate: There is a potential for an increase in plasma methotrexate.
- Ibuprofen should be used with caution in combination with:
  - Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin.
  - Anti-hypertensives and diuretics: NSAIDs may diminish the effect of these drugs. Diuretic can increase risk of nephrotoxicity of NSAIDs.
  - Corticosteroids: increased risk of gastrointestinal ulceration or bleeding.
  - Anti-platelets agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of
gastrointestinal bleeding.
Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increased plasma glycoside levels.
Ciclosporin: Increased risk of nephrotoxicity.
Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.
Lithium: There is evidence for potential increase in plasma levels of lithium.
Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolone may have increased risk of developing convulsions.

Use in Special Populations

Pregnant Women

Paracetamol

Epidemiological studies in human pregnancy have shown no ill effects due to Paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Ibuprofen

Whilst no teratogenic effects have been demonstrated in animal experiments the use of Ibuprofen oral suspension, should, if possible, be avoided during the first 6 months of pregnancy. During the 3rd trimester, ibuprofen is contraindicated as there is a risk of premature closure of the foetal ductus arteriosis possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. There is no experience of use of Ibugesic plus suspension in humans during pregnancy. Congenital abnormalities have been reported in association with NSAID administration in humans, although evidence of adverse effects during pregnancy following paracetamol treatment is lacking. This product is contraindicated during the third trimester of pregnancy, especially over the last few days before expected birth. Further, there is insufficient experience with the safety of use of ibuprofen in humans during pregnancy. Therefore, this product should not be used during the first 6 months of pregnancy unless the potential benefits to the patient outweigh the possible risk to the fetus and is contraindicated in the last three months of pregnancy.

Lactating Women

Paracetamol is excreted in breast milk but not in a clinically significant amount and available published data do not contraindicate breastfeeding. Ibuprofen and its metabolites can pass in very small amounts into breast milk. No harmful effects to infants are known.
In light of the above evidences it is not necessary to interrupt breastfeeding, for short-term treatment with the recommended dose of this product.
Geriatric Patients

NSAID-induced gastro-intestinal ulceration and/or bleeding may be more likely to cause serious consequences, including fatalities, in geriatric patients than in younger adults. In addition, elderly patients are more likely to have age-related renal function impairment, which may increase the risk of NSAID-induced hepatic and renal toxicity and may also require dosage reduction to prevent accumulation of the medication. Also, careful monitoring of the patient is recommended.

Effects on ability to drive & use machines

This product has no or negligible influence on the ability to drive and use machines.

Undesirable effects

Paracetamol

Very rare cases of serious skin reactions have been reported. Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily casually related to Paracetamol. With prolonged use or overdosage, hepatic necrosis, acute pancreatitis and nephrotoxicity have been reported.

Ibuprofen

The following frequencies are taken as a basis when evaluating undesirable effects:

- Very common: ≥ 1/10
- Common: ≥ 1/100 to < 1/10
- Uncommon: ≥ 1/1,000 to < 1/100
- Rare: ≥ 1/10,000 to < 1/1,000
- Very rare: < 1/10,000
- Not known: cannot be estimated from the available data

Hypersensitivity reactions have been reported and these may consist of:

- Non-specific allergic reactions and anaphylaxis
- Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea.
- Various skin reactions, e.g. pruritis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses, for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Hypersensitivity reactions

Uncommon: Hypersensitivity reactions with urticaria and pruritis.

Very rare: Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock).

Exacerbation of asthma and bronchospasm.

Gastrointestinal

The most commonly observed adverse events are gastrointestinal in nature.

Uncommon: Abdominal pain, nausea and dyspepsia.

Rare: Diarrhoea, flatulence, constipation and vomiting.

Very rare: Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis. Exacerbation of ulcerative colitis and Crohn's disease.

Nervous System

Uncommon: Headache
Very rare: Aseptic meningitis - single cases have been reported very rarely.

**Renal**
Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.

**Hepatic**
Very rare: Liver disorders.

**Haematological**
Very rare: Haematopoietic disorders (anemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

**Skin and subcutaneous tissue disorders**
Uncommon: Various skin rashes
Very rare: Severe forms of skin reactions such as bullous reactions, including Stevens-Johnson Syndrome, erythema multiforme and toxic epidermal necrolysis can occur.

**Immune System**
In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed.

**Cardiovascular and Cerebrovascular**
Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment. Clinical studies suggest that use of Ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme of India (PvPI) by calling on 1800 267 7779 (Cipla number) or you can report to PvPI on 1800 180 3024. By reporting side effects, you can help provide more information on the safety of this product.

### Overdose

**Paracetamol**
Liver damage is possible in adults who have taken 10 g or more of Paracetamol. Ingestion of 5 g or more of Paracetamol may lead to liver damage if the patient has risk factors.

**Risk Factors**
If the patient is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes.
If the patient regularly consumes ethanol in excess of recommended amounts.
If the patient is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

**Symptoms**
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the
absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.  

**Management**  
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.  

Treatment with activated charcoal should be considered if the overdose has been taken within one hour. Plasma Paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of Paracetamol, however, the maximum protective effect is obtained up to 8 hours’ post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 h from ingestion should be discussed with the NPIS or a liver unit.  

**Ibuprofen**  
In children ingestion of more than 400 mg/kg may cause symptoms. In adults, the dose response effect is less clear cut. The half-life in overdose is 1.5 – 3 hours.  

**Symptoms**  
Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning, metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.  

**Management**  
Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.  

### Pharmacological Properties

**Mechanism of Action**

Ibugesic plus Suspension is a combination of two well-established drugs: ibuprofen and paracetamol. Although the exact site and mechanism of analgesic action of paracetamol is not clearly defined, it appears that it induces analgesia by elevation of the pain threshold. The potential mechanism may involve inhibition of the nitric oxide pathway mediated by a variety of neurotransmitter receptors including N-methyl-D-aspartate and substance P.  

Ibuprofen is a propionic acid derivative with analgesic, anti-inflammatory and anti-pyretic activity. The drug's therapeutic effects as an NSAID result from its inhibitory effect on the enzyme cyclo-oxygenase, leading to reduction in prostaglandin synthesis. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid
on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use.

The exact mechanism of action of ibuprofen is thought to be through peripheral inhibition of cyclooxygenases and subsequent prostaglandin synthesis inhibition.

Pharmacodynamic Properties

Paracetamol
Paracetamol is an antipyretic analgesic. The mechanism of action is probably like that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

Ibuprofen
Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In human’s ibuprofen reduces inflammatory pain, swelling and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid (aspirin) on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use.

Pharmacokinetics Properties

Paracetamol
Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half-life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

Ibuprofen
Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. Peak plasma concentrations occur about 1 to 2 hours after ingestion with food or in 45 minutes if taken on an empty stomach. These times may vary with different dosage forms. The excretion is rapid and complete via the kidneys. The half-life of ibuprofen is about 2 hours. In limited studies, ibuprofen appears in the breast milk in very low concentrations. It is metabolised to two inactive metabolites and these are rapidly excreted in urine. About 1 percent is excreted in urine as unchanged Ibuprofen and about 14 percent as conjugated Ibuprofen. Ibuprofen is extensively bound to plasma proteins.
Non-Clinical Properties

- Animal toxicology or pharmacology

Data not available

Description

Ibugsic plus Suspension is a combination of two well established drugs: ibuprofen and paracetamol. Paracetamol is a non-salicylate antipyretic and non-opioid analgesic agent. Its chemical name is N-acetyl-p-aminophenol.

Ibuprofen, which is a member of the propionic acid group of nonsteroidal anti-inflammatory drugs (NSAIDs). Ibuprofen is a racemic mixture of S- and R-enantiomers. The chemical name for ibuprofen is (±)-2-p-isobutylphenyl) propionic acid. The molecular weight of ibuprofen is 206.28. Its molecular formula is C_{13}H_{18}O_{2}.

Pharmaceutical Particulars

- Incompatibilities

Not applicable

- Shelf life

As on pack

- Packaging Information

Ibugsic Plus Suspension........ Bottle of 60 ml
Ibugsic Plus Suspension........ Bottle of 100 ml

- Storage & handling instruction

Store in a cool place. Protect from light.
Shake well before use
Keep out of reach of children

Patient Counselling Information

What is Ibugsic Plus Oral Suspension?

Ibugsic Plus Suspension is combination of two well established drugs; ibuprofen and paracetamol. Paracetamol is a non-salicylate antipyretic and non-opioid analgesic agent. Ibuprofen is a propionic acid derivative NSAID, reduces inflammatory pain, swelling and fever.

Do not take Ibugsic Plus Suspension

- If your child is taking any other paracetamol or NSAIDs containing products, other flu, cold, cough or decongestant products.
- If your child is allergic (hypersensitive) to paracetamol or ibuprofen, or any of the other ingredients.
- If your child has had an allergic reaction or wheezing after taking aspirin or other non-steroidal anti-inflammatory painkillers.
- If your child has ever had a stomach ulcer or a history of bleeding into, or perforation of, the
intestine especially after previous NSAID treatment
If your child has ever had severe kidney, heart or liver problems
If your child is less than 3 months’ old

Before you take Ibugesic Plus Suspension tell your HCP about medication.
Always tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicine, even those obtained without a prescription, but especially medicines which:
are to treat ‘flu’ or a cold, containing paracetamol and/or ibuprofen. Do NOT give with other paracetamol products.
control nausea and vomiting (e.g. domperidone or metoclopramide)
reduce levels of cholesterol and other fats in the blood (e.g. colestyramine)
treat epilepsy (e.g. anti-convulsants)
Diuretics (drugs to help you pass water)
Medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
Lithium or Selective serotonin reuptake inhibitors (SSRI’s e.g. Fluoxetine) (used to treat mood disorders)
Methotrexate (used to treat rheumatoid arthritis, psoriasis and some cancers)
Zidovudine (used to help you pass water)
Corticosteroids (anti-inflammatory drugs, such as Hydrocortisone)
Cardiac glycosides (drugs used in the treatment of heart problems, such as Digoxin)
Ciclosporin or Tacrolimus (used to suppress the body’s immune system)
Mifepristone (used to terminate a pregnancy)
Quinolone antibiotics (used to treat a wide range of infections e.g. Ciprofloxacin)
any other Ibuprofen preparations, including those you can buy without a prescription.

How should I take Ibugesic Plus Suspension
Shake the bottle well before measuring the dose. This medicine should NOT be given if your child is less than 3 months old and weighs less than 5 kg.

<table>
<thead>
<tr>
<th>Age group</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants 3 - 6 months (weighing more than 5 kg)</td>
<td>2 - 2.5ml dose may be taken 3 times daily</td>
</tr>
<tr>
<td>&gt;6 months - 12 months</td>
<td>2 - 2.5ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>1- 4 years</td>
<td>4 - 4.5ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>4 - 7 years</td>
<td>4 - 8ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>7 - 10 years</td>
<td>8 - 10ml dose may be taken 3 to 4 times daily</td>
</tr>
<tr>
<td>10 -12 years</td>
<td>8 - 15ml dose may be taken 3 to 4 times daily</td>
</tr>
</tbody>
</table>

or as directed by the physician.

What are the possible side effects associated with Ibugesic Plus Suspension
Like all medicines, Ibugesic Plus Suspension can cause side effects although not everybody gets them. You should STOP giving this medicine and seek advice from your doctor if your child experiences a very rare allergic reaction, including skin rashes, increased sensitivity to light, swelling of the face and tongue, inflammation of the blood vessels, fever or shock. Skin and mucous membrane reactions may also occur.

Tell your doctor as soon as possible if you notice any of these:

- Allergic reactions including swelling of face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.
- Passing blood in their faeces (stools/motions)
- Passing black tarry stools
- Vomiting blood or dark particles that look like ground coffee
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, lightheadedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough urine.
- Stiff neck, headache, nausea, vomiting, fever and disorientation.

If your child’s skin starts to turn red or they develop a varied skin reaction or their skin starts to blister or peel, this is very rare

- Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting
- Yellowing of the eyes and/or skin

Severe sore throat with high fever or unexplained bleeding, bruising and tiredness.

Other unusual effects may include:

**Uncommon:**

- Headache.

**Rare**

- Ibuprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment
- Flatulence, diarrhoea or constipation.

**Very Rare**

- Occasionally hypersensitivity reactions may occur which can cause skin rashes
- Liver and kidney problems may occur with Ibuprofen
- Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated.

**Unknown**

A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

Long term use: people who use medicines containing paracetamol every day for a long time (several months or more) could get certain side effects, including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems.

Stop using Ibugesic Plus Suspension if you develop these symptoms and seek medical attention immediately.

**How should I store Ibugesic Plus Suspension**
General information about safe & effective use of drug.

Ibugesic Plus Suspension contain paracetamol antipyretic and non-opioid analgesic agent and ibuprofen, a nonsteroidal anti-inflammatory drugs (NSAIDs). Indicated in the treatment of pain and for reduction of fever in children < 12 years of age.

There is a risk of renal (kidney) impairment in dehydrated children.

You should discuss your child’s treatment with your doctor or pharmacist before giving this medicine if your child:

- has high blood pressure, kidney or liver problems
- has asthma or diabetes
- has lupus or mixed connective tissue disease
- has a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn’s disease or gastrointestinal bleeding
- has chickenpox

Speak to your doctor or pharmacist before taking this medicine if;

- you are in the first six months of pregnancy
- you are elderly
- you are trying to get pregnant. Ibuprofen belongs to a group of medicines which may impair fertility in women.

This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Pregnancy and breast-feeding

Ibuprofen should NOT be taken in the last 3 months of pregnancy, as it may be harmful to the unborn child. Pregnant women intending to use this product should seek medical advice before use as it should only be taken on doctor’s advice during the first 6 months of pregnancy.

What are the ingredients of Ibugesic Plus Suspension

The active ingredient is ibuprofen 100 mg and paracetamol 162.5 mg per 5 ml

Any other information

The effects of alcohol may be increased whilst taking Paracetamol Suspension. Avoid alcohol when taking this medicine.

Details Of Manufactures

Golden Cross Pharma Ltd.
Plot No.54 & 55 Sector-6A,
SIDCUL, Ranipur,
Distt. Haridwar (Uttarakhand) – 249 403. India
Registered Office:
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg, Lower Parel
Mumbai – 400 013, India
Details Of Permission Or Licence Number With Date

License No: 58/UA/LL/2019 Date: 18/11/2019

Date Of Revision

24/06/2020

IBUGESIC PLUS Oral Suspension

Source URL: https://www.ciplamed.com/content/ibugesic-plus-oral-suspension